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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,401	09/26/2006	Kenichi Koyakumaru	701063	1941
23460 7590 11/25/2009 LEYDIG VOIT & MAYER, LTD TWO PRUDENTIAL PLAZA, SUITE 4900 180 NORTH STETSON AVENUE CHICAGO, IL 60601-6731			EXAMINER CLARK, SARA E	
			ART UNIT 1612	PAPER NUMBER
			NOTIFICATION DATE 11/25/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/594,401	Applicant(s) KOYAKUMARU, KENICHI	
	Examiner SARA E. CLARK	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/30/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

FINAL REJECTION

Receipt is acknowledged of Applicants' Amendments and Remarks, filed 7/30/2009.

Claims 1 and 6 have been amended and incorporate no new matter.

No new claims have been added.

Thus, claims 1-9 now represent all claims currently pending and under consideration.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statement (IDS) submitted on 7/30/2009 was filed after the mailing date of the first Office Action on 4/2/2009. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

WITHDRAWN OBJECTIONS/REJECTIONS

Objections

Applicant's arguments, see Remarks, p. 6, filed 7/30/2009, with respect to the objections to the specification and claims 1-9, have been fully considered and are persuasive. Therefore, the objections have been withdrawn.

Rejections under 35 USC §102(b)

Applicant's arguments, see Remarks, pp. 6-7, filed 7/30/2009, with respect to the rejection of claims 1, 2, and 5 as anticipated under 35 USC §102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Rejections under 35 USC §103

Applicant's arguments, see Remarks, pp. 7-8, filed 7/30/2009, with respect to the rejection of claims 1-4 and 6-9 as obvious under 35 USC §103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Double Patenting Rejections

Applicant's arguments, see Remarks, p. 9, filed 7/30/2009, with respect to the obviousness-type double patenting rejection of instant claims 1-9 over claims 13, 15, 16, and 18 of copending application 10/594,164 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

The terminal disclaimer filed on 7/30/2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on application 10/594,164 has been reviewed and is accepted. The terminal disclaimer has been recorded.

NEW REJECTIONS

Claim Rejections - 35 USC § 112, First Paragraph

Scope of Enablement

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

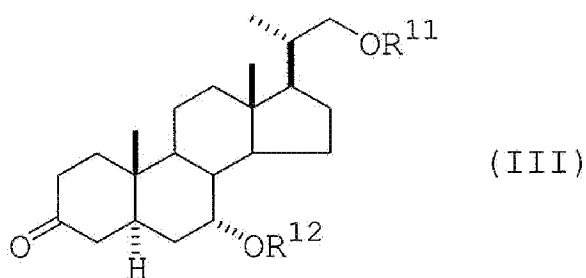
2. Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain palladium catalysts, does not reasonably provide enablement for all transition metals as catalysts, as recited by claims 1-9. The specification does not enable a person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

As recognized by MPEP 2164.01(a), "there are several factors to consider when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue." *In re Wands*, 8 USPQ2d 1400 (1988), sets out these factors, which include:

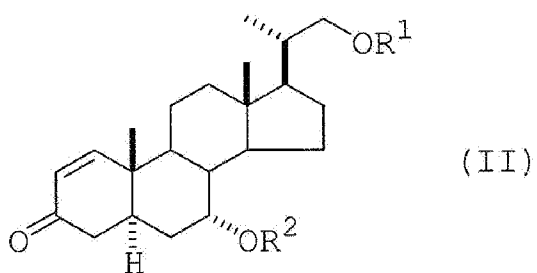
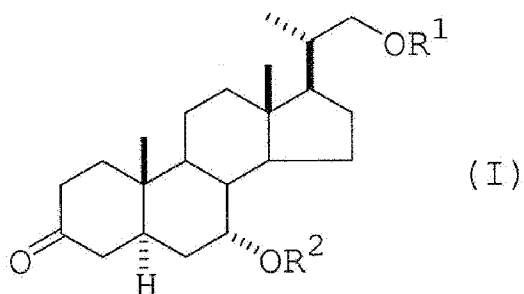
- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention.

The factors relevant to the present claims are analyzed below.

A. The Nature of the Invention. The claimed invention is a process for preparing a genus of 5 α -pregnane compounds of general formulae (III),



starting with a mixture of reactants corresponding to general formulae (I) and (II),



wherein R¹ and R² are each independently hydrogen or a hydroxyl-protecting group, by selectively hydrogenating the C₁-C₂ double bond of formulae (II) with a transition metal catalyst.

B. The Breadth of the Claims. By reciting any transition metal catalyst, the scope of the claims extends well beyond the disclosure, encompassing reactions which have not been shown to be capable of being catalyzed by the full range of the catalysts claimed. With the exception of palladium/carbon (Pd/C) (see specification pp. 25-26, Examples 1 and 2), it has not been demonstrated that any transition metal catalyst would promote the reaction of the claimed process. The nature of the catalyst is essential to the reaction and the selection is critical. While the mechanism is not known with certainty, the reaction is driven by steric factors and the substrate must intimately interact with the transition metal catalyst in an ordered fashion.

C. The State of the Prior Art and the Level of Predictability in the Art. The efficacy of a given catalyst in organic synthesis is unpredictable because it has not been established that all transition metal catalysts, or even all palladium compounds, would effectively catalyze the claimed reaction. For example, some hydrogenation catalysts provide a solvated electron source (e.g., tris(dibenzylideneacetone)dipalladium), whereas others such as Pd/C present an electron source as a planar adsorptive surface, such that the selective catalytic reduction (hydrogenation) of a sterically-hindered double bond can occur by different mechanisms, resulting in different reaction times, intermediates, and products.

D. The Amount of Direction or Guidance and Presence of Working Examples. The only direction or guidance present in the specification relating to the use of transition metal catalysts is found on p. 14, line 28 to p. 15, line 7:

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As the metal of the transition metal catalyst to be used for the hydrogenation, for example, ruthenium, rhodium, iridium, nickel, palladium, platinum and the like can be mentioned. Of these, nickel, palladium and platinum are preferable, and palladium is most preferable. The form of the transition metal catalyst may be a complex catalyst (e.g., tetrakis(triphenylphosphine) palladium, palladium acetate) that dissolves in a reaction system, or a heterogeneous catalyst (for example, palladium-carbon, palladium hydroxide, palladium black, platinum oxide) that does not dissolve in a reaction system. However, a heterogeneous catalyst is preferable, because it is easily separated from the reaction system, and palladium-carbon and palladium black are particularly preferable.

While many transition metal compounds and complexes are identified, the working examples employ only palladium/carbon (Pd/C) (see specification pp. 25-26, Examples 1 and 2). Therefore, the disclosure does not reasonably support the use of any transition metal as the selective hydrogenation catalyst of the claimed process, and provides no direction or instruction for the preparation of the claimed compounds employing catalysts other than Pd/C.

E. The Quantity of Experimentation Needed and the Level of Skill in the Art.

While the level of skill in organic synthesis is high, undue experimentation would be required to prepare the claimed compounds using any transition metal as the selective hydrogenation catalyst, such that, without further guidance or working examples, one of ordinary skill in the art would not reasonably be enabled to practice the invention commensurate with the full scope of the claims.

CONCLUSION

Claims 1-9 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARA E. CLARK whose telephone number is (571) 270-7672. The examiner can normally be reached on Mon - Thu, 7:30 am - 5:00 pm (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARA E. CLARK/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612